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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,097	01/16/2001	David A Shafer	1414.501U2	2981

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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 10/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/744,097	Applicant(s) SHAHER, DAVID A	
	Examiner Jeffrey Fredman	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 and 40-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group IV, claims 28-39 in the reply filed on September 13, 2004 is acknowledged.

Claim Rejections - 35 USC § 112

2. Claims 28-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite what is meant by "detecting the presence or said reporter or reporters" in step e) of claim 28. It appears that the first "or" is a typographical error which should be "of".

In claims 38 and 39, the use of the terms "RING-TAIL" is unclear since no discussion of what constitutes this probe is discussed in these claims. Further, the steps of the claims are written in confusing language which makes it vague and indefinite what, precisely, is occurring in these interactions. For example, in claim 38, there is no discussion of where the ring tail and wrap probe specifically hybridize in step c). So reading this element, it is unclear which portion of the wrap probe interacts with which portion of the ring tail probe. In particular, the claim makes little sense relative to figure 18, for example, because it is vague and indefinite how the first terminal linker is linked to form the closed circle. Similar clarity problems exist for claim 39, where it is entirely unclear which element is interacting with which other element. Step (i) for example, is particularly unclear. So it is suggested that these claims be rewritten to

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more precisely reflect what element of what probe is hybridizing with which end of which other probe.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 28-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Urdea et al (U.S. Patent 5,681,697).

Urdea teaches a method for detecting a target nucleotide sequence (see abstract) comprising:

a) rendering the target nucleotide sequence substantially single stranded to give a single-stranded target nucleotide sequence (see figure 1 and column 11, lines 37-39, where Urdea teaches the use of single stranded target sequence),

b) hybridizing the single stranded target nucleotide sequence with a nucleic acid probe (see figure 1 and column 11, lines 37-45) where the nucleic acid probe comprises a central sequence complementary to the target sequence and further comprises a probe linker at one terminal end which probe linker comprises a single stranded nucleotide sequence that does not hybridize to the target sequence (see figure 1 and column 10, line 61 to column 11, line 7, where the label extender probe comprises a

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region which hybridizes to the target and a second region which does not hybridize to the target),\

c) washing to remove any unbound probe (see figure 1 and column 11, lines 57-59),

d) joining the reporter to the linker (see figure 1 and column 11, lines 49-65),

e) detecting the presence of said reporter to indicate the target sequence (see figure 1 and column 11, line 65).

With regard to claim 29, Urdea teaches a first terminal probe linker (see figure 1).

With regard to claim 30, Urdea teaches a probe which comprises a first and second terminal probe linker (see figure 16, where the LE has an X and Y region that hybridizes to the Amp1 probe).

With regard to claim 34, Urdea teaches a direct interaction between the reporter and terminal probe linker (see figure 1).

With regard to claims 31, 32, 33, 35 and 36, Urdea teaches a multi-linking unit (which is a reporter array) which is double stranded in the interaction with the LE probe which is interposed between the reporter linker and the terminal linkers, where the multilinking unit of figure 8, for example, comprises single stranded regions which hybridize with multiple reporter probes placed end to end which hybridize to the unit which is hybridized to the terminal linkers and where there is a "terminator" or terminal reporter probe (see figures 1, 8 and 16).

With regard to claim 37, the reporter is a short oligonucleotide having a label unit (see figure 1).


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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Jeffrey Fredman
Primary Examiner
Art Unit 1637

10/22/07